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Regulating Food and Drug Companies Privately:

A Review of Lanham Act Cases Brought Against FDA-Regulated Products ¹

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I. Introduction

Suppose you are a laboratory biologist studying a new ingredient for an antacid when you discover that the substance has a curious side effect: no matter how much you feed the lab rats, they do not gain weight. Skeptically, you think this must be a fluke, or maybe that the new ingredient is eating away the rats' insides. But then you set up some controlled experiments and find that it was not a fluke. The drug stabilizes the rats' body fat levels and leaves them otherwise healthy. Realizing you may have stumbled upon the greatest pharmaceutical discovery in history, along with untold fame and fortune, you set up a company that will dwarf Microsoft. You call your startup "Newco" to confuse the corporate lawyers and concoct the crafty marketing name "Taferomon" for your miracle drug.¹ Taferomon has so much potential that you have no trouble with the greedy venture capitalists. Money is not a problem and human clinical trials prove that Taferomon is effective and has just a few minor side effects. Thus after flying through all three phases of Food and Drug Administration ("FDA") approval in eight years, Taferomon is about to hit the shelves and Newco has gone public.

¹Course paper for Food and Drug Law, Harvard Law School, Mr. Peter Barton Hutt, March 5, 2001.

¹Note that read backwards, Taferomon is "no more fat." The author cannot claim full credit for this ingenuity; inspiration came from an early competitor of the hair growth stimulant Rogaine which called itself Riahom, or backwards, "mo hair." *See* Upjohn Co. v. Riahom Corp., 641 F. Supp. 1209, 1216 (D.Del. 1986).

At breakfast one morning though you open the newspaper and turn on CNBC to see what the Street has to say about Newco. Instead of rosy predictions you see a newspaper advertisement touting a new miracle weight loss pill that works even better than Taferomon and a television commercial for a fat-reducing cream based on the same active ingredient as Taferomon. You know these claims, and a host of others that will follow, cannot all be true and that these fly-by-night companies must be violating some FDA regulations. But you also know that having those products and claims about your product out on the market for just a few months can kill your profits. So although you immediately have your lawyers asking the FDA to take action, the agency may be unable or unwilling to respond. The lawyers suggest that you may have a better alternative: bringing a Lanham Act unfair competition action against your competitors. Rather than relying on FDA enforcement, increasing numbers of food, drug, cosmetic, and medical device manufacturers in your position have used the Lanham Act to obtain prompt relief from false or misleading claims about their products or a competitor's products.

II. Regulatory and Statutory Background

A. Food, Drug & Cosmetic Act

The Federal Food, Drug, and Cosmetic Act (“FDCA”)² authorizes the FDA to regulate the labeling and marketing of foods, drugs, cosmetics, and medical devices. While the FDA exclusively regulates both la-

²21 U.S.C. §§ 301-397 (2000).

belonging and advertising for prescription drugs, however, the Federal Trade Commission (“FTC”) regulates advertising for over-the-counter (“OTC”) drugs, food, and cosmetics.³ Enforcement authority under the FDCA lies with the government: “[e]xcept as provided in subsection (b) [regarding suits brought by states], all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.”⁴ Thus if a firm believes that a competitor is violating the FDCA and thereby disadvantaging the complaining firm in the market or infringing its economic rights, “the indicated first step is a complaint to the FDA.”⁵

Although a firm might succeed in persuading the FDA to pursue an enforcement action, the agency may not have the resources to do so even in a meritorious case. Throughout the FDA’s history, budgetary considerations have limited the agency’s regulatory activity, particularly regarding economic violations of the FDCA.⁶ “Perhaps in an effort to justify budget increases (or at least to prevent further budget cuts), the agency has forthrightly stated that it simply will not enforce certain parts of the act.”⁷ Beyond concerns about limited resources, the FDA may have little interest in pursuing certain violations.⁸ Moreover, an aggrieved firm cannot challenge an FDA refusal to take action because the agency has complete discretion.

³See FDA-FTC Memorandum of Understanding, 36 Fed. Reg. 18,539 (Sept. 16, 1971).

⁴21 U.S.C. § 337(a) (2000).

⁵Thomas J. McGrew & Donald O. Beers, *When the FDA Takes No Action Against Violations of the Federal Food, Drug, and Cosmetic Act, Can a Private Cause of Action Be Brought Under Section 43(a) of the Lanham Act?*, 47 FOOD & DRUG L.J. 1 (1992).

⁶From FY 1998 to FY 1999, FDA product seizures dropped from 35 to 25. Injunctions were also down, from 11 in 1998 to eight in 1999, and there were no prosecutions in either year. See James G. Dickinson, *Less FDA Enforcement/Surveillance in 1999*, MEDICAL MARKETING & MEDIA, June 1, 2000, at 30. These decreases were “presumably the result of successive annual “level funding” budgets from Congress.” *Id.*

⁷Peter Barton Hutt, *FDA Reduces Economic Regulation of Food Industry*, LEGAL TIMES OF WASHINGTON, Aug. 30, 1981, at 31.

⁸Comparative claims and negative advertisements, for example, may be of little significance to the FDA. “For example, while a company may be significantly injured by a competitor misrepresenting its FDA compliance status, the FDA is unlikely to use its resources against this competitor.” Jeffrey N. Gibbs, *Medical Device Promotional Activities and Private Litigation*, 47 FOOD & DRUG L.J. 295, 296 (1992).

In *Heckler v. Chaney*,⁹ the Supreme Court held that an FDA refusal to take requested enforcement actions is not subject to judicial review under the Administrative Procedure Act.

Predictably, firms have tried to enforce the FDCA privately but that approach also has failed. Although all federal appellate courts have not considered the issue, it has become well established that the FDCA does not create a private cause of action.¹⁰ Some courts have noted that Congress “considered and rejected a version [of the FDCA] which would have allowed a private cause of action for damages.”¹¹ One court reasoned that if it recognized such a right,

“the major advantages of enforcement through the [FDA] would be lost, including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy.”¹² Courts also have held that there is no implied private cause of action to enforce the FDCA under state law.¹³

B. Lanham Act

Nevertheless, firms like our hypothetical Newco with millions of dollars at stake have increasingly decided

⁹470 U.S. 821 (1985).

¹⁰*See, e.g.*, *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997); *Bailey v. Johnson*, 48 F.3d 965, 967 (6th Cir. 1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3rd Cir. 1994), *cert. denied*, 513 U.S. 965 (1994); *Mylan Lab., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), *cert. denied*, 510 U.S. 1197 (1994); *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976). In *Merrell Dow Pharm. v. Thompson*, 478 U.S. 804 (1986) (holding that there is no federal jurisdiction where a plaintiff asserts an FDCA violation as an element of a state cause of action), the parties agreed with the lower court that there was no private cause of action so the Supreme Court assumed that was correct for the purposes of its opinion.

¹¹*Bailey*, 48 F.3d at 968, *quoting* *National Women’s Health Network, Inc. v. A.H. Robins Co.*, 545 F. Supp. 1177, 1179 (D. Mass. 1982).

¹²*Id.*, *quoting* *National Women’s Health Network*, 545 F. Supp. at 1180.

¹³*See, e.g.*, *Animal Legal Defense Fund v. Provini Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass. 1986), *aff’d mem.*, 802 F.2d 440 (1st Cir. 1986) (stating that a state “cannot confer on private persons the power to enforce a federal statute whose enforcement Congress left to federal administrative agencies”).

that they cannot rely on the possibility of FDA enforcement and therefore turned to the Lanham Act¹⁴ as a private self-help remedy. The Lanham Act provides companies a powerful tool for relief against unfair competition. Most pertinently, section 43(a) of the Lanham Act states that:

(1) Any person who... uses in commerce any word, term, name, symbol, or device... or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which...

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.¹⁵

Under this provision, a company can sue a competitor¹⁶ for false claims regarding the goods or services of *either* party.¹⁷

A plaintiff bringing a conventional Lanham Act claim based on false or misleading advertising must prove five elements by a preponderance of the evidence: (1) that the defendant made false or misleading statements; (2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) that the deception is material in that it is likely to influence purchasing decisions; (4) that the goods traveled in interstate commerce; and (5) that there is a likelihood of injury to the plaintiff in

¹⁴15 U.S.C. §§ 1051-1072, 1091-1096, 1111-1129 (2000).

¹⁶Although consumers do not have standing to sue under section 43(a), the public's interest in truthful advertising nevertheless can be advanced through the competitor's efforts to prevent false or misleading statements. In *Coca-Cola Co. v. Procter & Gamble Co.*, 822 F.2d 28, 31 (6th Cir. 1987), for example, the court stated that "[p]rotecting consumers from false or misleading advertising... is an important goal of the [Lanham Act] and a laudable public policy..." See also Charles J. Walsh & Marc S. Klein, *From Dog Food to Prescription Drug Advertising: Litigating False Scientific Establishment Claims Under the Lanham Act*, 22 SETON HALL L. REV. 389, 411-412 (1992).

¹⁷This was clarified by a 1988 amendment. Prior to 1988, some courts interpreted section 43(a) to apply only to misrepresentations about one's own products. See, e.g., *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 n.1 (2d Cir. 1991).

terms of reduced sales, loss of good will, and other factors.¹⁸ If the plaintiff can prove, however, that the challenged claim is literally false, “a court may grant relief without considering whether the buying public was misled.”¹⁹

Because Lanham Act plaintiffs believe their competitors’ marketing campaigns are injuring them in the marketplace, they frequently ask for temporary restraining orders, expedited discovery, and preliminary injunctions. The result is “fast-paced litigation” that tends “to proceed much faster than other civil litigation because the goal is to obtain prompt relief.”²⁰ As one court noted about an antacid maker who was challenging a rival’s product effectiveness claims, the plaintiff “seeks what it normally promises to provide – fast and effective relief.”²¹ Section 34(a) of the Lanham Act authorizes the court to enjoin false or misleading statements.²² *As discussed in*

Section IV, *infra*, however, courts have exercised their equitable powers under that provision to order a wide range of remedies.

III. Limitations On Lanham Act Claims

Courts will not use their remedial powers, however, to step into the FDA’s shoes to enforce the FDCA. “It

¹⁸ *See, e.g.*, Warner-Lambert Co. v. BreathAsure Inc., 204 F.3d 87, 91-92 (3d Cir. 2000); Summit Tech., Inc. v. High Line Med. Instruments Co., 933 F. Supp. 918, 929 (C.D. Cal. 1996).

¹⁹ Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc., 19 F.3d 125, 129 (3d Cir. 1994). The Second Circuit, where many of these cases are tried, boils the analysis down to the following:

[A] plaintiff must demonstrate by a preponderance of the evidence that an advertisement is either literally false or that the advertisement, though literally true, is likely to mislead consumers.... Where the advertising claim is shown to be literally false, the court may [grant relief] without reference to the advertisement’s impact on the buying public.

McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d at 1549.

²⁰ Gibbs, *supra* note 8, at 300.

²¹ Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 2000 WL 1946673 at *1 (D.N.J. Dec. 22, 2000).

²² Section 34(a) of the Lanham Act provides: “The... courts... shall have power to grant injunctions, according to the principles of equity and upon such terms as the court may deem reasonable, to prevent... a violation [of section 43(a)].” 15 U.S.C. § 1116(a) (2000).

is not for a court to force the FDA to interpret, apply, and enforce its regulations in a manner determined by the court to fairly effectuate the [FDCA's] policies.”²³

A. Implied Statements of FDA Approval Generally Not Actionable

Returning to the Taferomon example, assume that Quackco markets a weight control pill that has not been approved by the FDA but claims to have the same properties as Taferomon.²⁴ Newco would not succeed on a Lanham Act claim suggesting that the act of placing the drug on the market implies falsely that the Quackco drug has proper FDA approval.²⁵ In *Mylan Laboratories, Inc. v. Matkari*,²⁶ a drug manufacturer failed in such a claim against generic drug makers because the plaintiff did not point to any affirmative misrepresentations of FDA approval by the defendants. The court found Mylan’s theory “too great a stretch under the Lanham Act,” reasoning that allowing such a theory would “in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce the [FDCA].”²⁷ A section 43(a) plaintiff must “point to *some* claim or misrepresentation that is reasonably clear from the face of the [offending] advertising or package inserts.”²⁸

This requirement may be met, however, if the competitor’s statement “comes very close” to a “bald representation of FDA approval.”²⁹ In *Summit Technology, Inc. v. High Line Medical Instruments*,³⁰ for example, an ophthalmological laser manufacturer sued an importer of such systems who made statements

²³*Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990), *citing* *Cutler v. Kennedy*, 475 F. Supp. 838, 856-57 (D.D.C. 1979).

²⁴The hypothetical examples used here are simplified for illustrative purposes; presumably, in some of the situations proposed the FDA would use its enforcement powers to protect public health.

²⁵*See Mylan Lab., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), *cert. denied*, 510 U.S. 1197 (1994).

²⁶*Id.*

²⁷*Id.* (noting also that Mylan “is not empowered to enforce independently the FDCA”).

²⁸*Id.*

²⁹*Summit Tech., Inc. v. High-Line Med. Instruments, Co.*, 933 F. Supp. 918, 936 (C.D. Cal. 1996).

³⁰*Id.*

in a press release regarding FDA approval of certain devices made by the plaintiff. The defendant did not provide a qualification noting that those devices mentioned were not the same as the devices marketed by the defendant, thereby leaving a false impression that the defendant was selling FDA-approved devices.³¹ By allowing Summit's claim, the court thus found that High Line's statements crossed the line between a failure to disclose non-approval, as in *Mylan*, and an affirmative representation of approval. Employing a theory similar to that used by the *Mylan* and *Summit* plaintiffs, the plaintiff in *Lymphomed, Inc. v. Professional Compounding Centers of America, Inc.*,³² alleged that the defendant's false "statement" was the act of doing business in violation of the FDCA.³³ Lymphomed, manufacturer of the orphan drug pentamidine, brought suit against the defendant, whose employees were selling ingredients for pentamidine to pharmacists and representing to them that compounding the orphan drug was lawful. Lymphomed's lawyers later noted that:

It seemed clear that [the defendant's] shipment of pentamidine directly violated the FDCA. Although the FDA agreed to investigate,... there is a long time... between investigation... and... regulatory action. Indeed, there was no assurance that the FDA would ever take regulatory action. Lymphomed concluded that, given the commercial environment, it could not wait to see whether the FDA would eventually take action.³⁴

Although the court granted an injunction in *Lymphomed*, it did so based on pentamidine's orphan drug status.³⁵ *Mylan* would appear to preclude Lymphomed's theory because the plaintiff did not point to a clear false or misleading representation. Indeed, even the *Lymphomed* court itself stated that: "There is clearly no private right of action for [the defendants] not having complied with the [FDCA] to ship the drug. The question here is [the plaintiff's orphan drug] exclusivity.... Nobody chartered [the plaintiff] to protect the

³¹See *id.*

³²Civ. No. H-89-1792 (S.D. Tex. May 23, 1989).

³³See McGrew, *supra* note 5, at 5.

³⁵See Gibbs, *supra* note 8, at 303.

public.”³⁶

B. Claim Cannot Require Original Interpretation of FDCA

A complicating factor in the *Lymphomed* suit was that the parties sharply disputed whether the defendant had directly violated the FDCA.³⁷ This illustrates why courts have imposed another limitation on Lanham Act plaintiffs: a section 43(a) claim cannot require original interpretation of the FDCA. That is the role of the FDA, not the court in a private litigation.

Suppose Quackco markets as a dietary supplement a product that has chemical properties similar to Taferomon. A court would be unlikely to find Quackco in violation of section 43(a). Analogous circumstances led to Lanham Act litigation in *Braintree Laboratories, Inc. v. Nephro-Tech, Inc.*³⁸ In that case, the defendant Nephro-Tech marketed a “dietary supplement” with the same active ingredient as the plaintiff’s kidney disease drug. Braintree argued that Nephro-Tech’s “dietary supplement” designation was a false or misleading statement violating section 43(a). Because the case turned on the statutory definition of “dietary supplement,” the court found that Braintree’s claim was a “classic misbranding [claim]... solely for resolution by the FDA.”³⁹ As the court noted, “even if it were determined in litigation that [defendant’s drug] did not meet some independent, lay understanding of the term “dietary supplement,” defendants might not be able to remove the term from its label without violating the FDCA.”⁴⁰

³⁶Lymphomed, No. H-89-1792, *quoted in* Gibbs, *supra* note 8, at 303.

³⁷See Gibbs, *supra* note 8, at 307 n.40.

³⁸1997 WL 94237 at *1 (D. Kan. Feb. 26, 1997).

³⁹*Id.* at *7.

⁴⁰*Id.*

Similarly, the Third Circuit refused to encroach on FDA turf in *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*⁴¹ There, the defendant had made claims that the demulcents in its Pediatric 44 cough syrup, which the defendant had listed as inactive ingredients, enabled the medicine to work immediately after swallowing. The plaintiff alleged that the demulcents therefore should be listed as active ingredients as per FDA regulations and that the defendant violated section 43(a) by not listing them as such. Ruling that the defendant's labeling was not false, the court reasoned that "[t]he FDA has not found conclusively that demulcents must be labeled as active or inactive ingredients... [and] the agency should be given the first chance to exercise [its] discretion or to apply [its] expertise."⁴² "[W]hat the [FDCA] and the FTC Act do not create directly, the Lanham Act does not create indirectly, at least in cases requiring original interpretation of these Acts or their accompanying regulations."⁴³ Furthermore, the *Sandoz* court recognized the dilemma faced by a plaintiff seeking redress for a competitor's FDCA violations but indicated that the Lanham Act is not the solution:

Sandoz is free to petition the FDA to investigate these alleged labeling violations. Sandoz represents that it has embarked upon this path already. The fact that it has been unable to get a quick response from the FDA, however, does not create a claim for Sandoz under the Lanham Act.⁴⁴

C. Claim Can Succeed If Direct Interpretation Of FDCA Is Not Required

Nevertheless, a false or misleading statement is actionable under the Lanham Act even if it violates the

⁴¹902 F.2d 222 (3d Cir. 1990).

⁴²*Id.* at 230-31 (noting also that the plaintiff's "position would require [the court] to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations").

⁴³*Id.* at 231. *See also* Summit Tech., Inc. v. High-Line Med. Instruments, Co., 933 F. Supp. 918 (C.D. Cal. 1996). The *Summit Technology* court upheld Lanham Act claims based on whether the parties' medical devices were "identical," whether the defendants' devices had FDA approval, and whether a defendant's machine was new because those claims demanded factual inquiries that did not require the court to "tread on the FDA's exclusive domain." *Id.* at 935, 936, 940. However, the court dismissed claims that involved inquiring into whether the FDA permitted certain uses of the defendants' devices because those claims were "far more nebulous." *Id.* at 936.

FDCA. In *Mylan*, for example, the court allowed an allegation that the defendant’s “bioequivalence” claim was false or misleading, even though FDA regulations defined that term, because the plaintiff pleaded “sufficiently particularized” facts to support its claim.⁴⁵ Likewise, the plaintiff in *Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.*,⁴⁶ asserted an independent basis for its claim. The defendant represented its product as “100% orange juice from concentrate” even though it contained various additives.⁴⁷ Although FDA regulations defined “orange juice from concentrate,” Grove Fresh “relie[d] on the [definition] merely to establish the standard or duty which defendants allegedly failed to meet.”⁴⁸

IV. Lanham Act Cases Regarding Performance And Efficacy Claims

A majority of Lanham Act cases brought against food and drug companies, however, involve competitor’s statements regarding the performance or efficacy of one or both of the party’s products. Product claims take several forms. A scientific establishment claim, for example, “represents that there is scientific evidence which establishes the truth of the statement.”⁴⁹ A non-establishment claim, on the other hand, includes an objective representation about a product without an express representation that some scientific evidence supports the statement.⁵⁰ Some claims regard the superiority of one product over another;⁵¹ others simply refer to desired qualities a product purports to possess.⁵²

⁴⁵*Mylan Lab., Inc. v. Matkari*, 7 F.3d 1130, 1138 (4th Cir. 1993).

⁴⁶720 F. Supp. 714, 716 (N.D. Ill. 1989).

⁴⁷*Id.*

⁴⁸*Id.* at 716. Similarly, the court in *Potato Chip Institute v. General Mills, Inc.*, 461 F.2d 1088 (8th Cir. 1972), found that the phrase “potato chip” was misleading when used by the defendant to describe its product which was made of both raw potatoes and dehydrated potatoes. Because “the past experience of the consumer so shades the term [“potato chip”] with a raw potato overlay,” thus establishing an independent basis for the plaintiff’s claim, the lower court’s discussion regarding the applicable FDA regulations was irrelevant. *Id.* at 1089, 1090 n.1.

⁴⁹*Thompson Med. Co. v. Ciba-Geigy Corp.*, 643 F. Supp. 1190, 1196 (S.D.N.Y. 1986). *See also* Walsh, *supra* note 16, at 419-420 (noting that *Thompson Med. Co.* marked the entrance of the concept of an establishment claim into Lanham Act jurisprudence).

⁵⁰*See* Walsh, *supra* note 16, at 420.

⁵¹*See, e.g.*, *Procter & Gamble v. Cheesebrough-Pond’s, Inc.*, 747 F.2d 114 (2d Cir. 1984) (regarding hand and body lotion superiority claims such as, “relieves dry skin better than any leading lotion”).

⁵²*See, e.g.*, *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 2000 WL 1946673 at *1 (D.N.J. Dec. 22, 2000) (challenging the accuracy of the name of defendant’s Mylanta Night Time Strength antacid).

A. Plaintiff's Burden

Although the FTC has authority to find that an inadequately substantiated advertising claim regarding an OTC drug is deceptive or misleading,⁵³ “[a] Lanham Act plaintiff, on the other hand, is not entitled to the luxury of deference to its judgment.”⁵⁴ “The burden of proving “literal falsity” varies depending on the nature of the challenged claim.”⁵⁵ For non-establishment claims, where the defendant does not refer to scientific tests or studies, “each plaintiff bears the burden of showing that a challenged advertisement is false or misleading, not merely that it is unsubstantiated by acceptable tests or other proof.”⁵⁶ For establishment claims, however, a plaintiff can prove literal falsity by demonstrating that the relied upon studies “are not sufficiently reliable to permit one to conclude with reasonable certainty that they established” the challenged claim.⁵⁷ Furthermore, some courts hold that a product claim may be found “false by necessary implication.”⁵⁸

If the plaintiff can establish that a product claim is literally false, then the court may grant relief without

⁵³See 15 U.S.C. § § 45 & 52 (2000); *see also* Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 227 (3d Cir. 1990).

⁵⁴Sandoz, 902 F.2d at 228.

⁵⁵Zeneca Inc. v. Eli Lilly and Co., 1999 WL 509471 at *31 (S.D.N.Y. July 19, 1999).

⁵⁶Procter & Gamble Co. v. Cheesebrough-Pond’s, Inc., 747 F.2d at 119. *See also* Sandoz, 902 F.2d at 228. A recent case, however, picked up on an issue left unaddressed in *Sandoz* and suggested that a *completely unsubstantiated* advertising claim can violate the Lanham Act even without proof that consumers were actually misled. *See* Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 2000 WL 1946673 at *9 (D.N.J. Dec. 22, 2000) (applying this principle where the advertiser relied on “pure speculative hypothesis” and did “not appear to have at least some semblance of support” for its claim).

⁵⁷McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544, 1549 (2d Cir. 1991).

⁵⁸Novartis, 2000 WL 1946673 at *10-11 (finding the product name “Mylanta Night Time Strength” false by necessary implication where the company making the claim presented no evidence to show that the antacid was formulated specifically for night use). *See also* Warner-Lambert Co. v. BreathAsure, Inc., 204 F.3d 87, 92 (3d Cir. 2000) (finding the trade name BreathAsure false by necessary implication because the products so named were ineffective in reducing bad breath). *But see* Novo Nordisk A/S v. Becton Dickinson and Co., 997 F. Supp. 470, 473 n.7 (S.D.N.Y. 1998) (distinguishing Third Circuit law and stating that “claims of implicit falsity belong within the “likely to mislead and confuse” category of claims”).

considering whether consumers were misled.⁵⁹ If however the challenged claim is literally true, then the plaintiff must show that it is nevertheless likely to confuse or mislead consumers.⁶⁰ This is accomplished through the use of consumer surveys to show actual consumer confusion or deception.⁶¹

Some courts have adopted a presumption shifting the burden of proof to the defendant where the plaintiff can show that the defendant intended to mislead the public.⁶² Before invoking this presumption, however, the plaintiff must prove that the defendant's conduct was "deliberate" and of an "egregious nature."⁶³ Thus in *Johnson & Johnson-Merck Consumer Pharmaceuticals Co. v. Rhone-Poulenc Rorer Pharmaceuticals, Inc.*,⁶⁴ even though the plaintiff presented evidence that the defendant's "strongest antacid there is" claim intended to mislead, the defendant's conduct did not rise to the level of deliberate and egregious conduct. The court held that the plaintiff's evidence of intent "only show[ed] an intent to mislead, or to create a misleading halo effect, of a kind that is unfortunately common in the antacid industry."⁶⁵

B. Literally False Product Claims

1. Weak Scientific Support

Suppose Quackco markets a drug under the less subtle name "Male Gut Reducer" that like Taferomon

⁵⁹See, e.g., *Warner-Lambert Co. v. BreathAsure, Inc.*, 204 F.3d at 92; *McNeil-P.C.C.*, 938 F.2d at 1549.

⁶⁰See, e.g., *Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc.*, 19 F.3d 125, 129 (3d Cir. 1994); *McNeil-P.C.C.*, 938 F.2d at 1549.

⁶¹See, e.g., *Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc.*, 19 F.3d at 129-130. A plaintiff "cannot obtain relief by arguing how consumers *could* react; it must show how consumers *actually do* react." *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229 (3d Cir. 1990).

⁶²See, e.g., *Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer*, 19 F.3d at 131-32; *Johnson & Johnson-Merck Consumer Pharm. Co. v. SmithKline Beecham Corp.*, 960 F.2d 294, 298-99 (2d Cir. 1992).

⁶³*Johnson & Johnson-Merck Consumer Pharm. Co. v. SmithKline Beecham Corp.*, 960 F.2d at 298-99.

⁶⁴19 F.3d 125 (3d Cir. 1994).

⁶⁵*Id.* at 132.

stabilizes, but does not reduce, body fat levels. Newco asserts, however, that Quackco's product is in no way specially-formulated for men and that although it may stabilize, it does not reduce fat. Newco would have a strong section 43(a) case based on these facts. In *Warner-Lambert Co. v. BreathAsure, Inc.*,⁶⁶ for example, the plaintiff, a manufacturer of various breath freshening products, challenged the defendant's trade name "BreathAsure" because the name "implies assurance where there is no basis for it."⁶⁷ At trial, the defendant stipulated that scientific studies demonstrated that its products were not effective in reducing bad breath. Because it was uncontested that the defendant's efficacy claim had no scientific basis, the court found the trade name literally false.⁶⁸ Similarly, the court in *Upjohn Co. v. Riahom Corp.*⁶⁹ also used a lack of scientific foundation to find false the defendant's claim that its hair growth treatment promoted hair growth. The defendant admitted to the court, however, that its product merely "promotes a fuller, thicker head of hair and nourishes the scalp."⁷⁰ In a much different context, Ralston Purina claimed that its Puppy Chow dog food can reduce the severity of canine hip dysplasia.⁷¹ Ralston's competitor, Alpo, brought a Lanham Act suit alleging that the claim was based on bad science. The court agreed and found Ralston's claim false.⁷²

2. The Role of FDA Findings

More recently, a court has considered the fact that the FDA has not approved a drug claim as "persuasive

⁶⁶204 F.3d 87 (3d Cir. 2000).

⁶⁷*Id.* at 90.

⁶⁸*Id.* at 96.

⁶⁹641 F. Supp. 1209 (D. Del. 1986).

⁷⁰*Id.* at 1224. The court also stated that the defendant's claim that its minoxidil-containing product was a cosmetic may have been literally false because the FDA had decided that any minoxidil compound promoted for hair growth is a drug. *See id.* at 1223.

⁷¹*See* Alpo Petfoods, Inc. v. Ralston Purina Co., 913 F.2d 958 (D.C. Cir. 1990).

⁷²Among other things, Ralston's scientists had "improperly combined unrelated data to attain statistical significance, ignored warnings... concerning the validity of its data, discarded inconsistent results, failed to properly control variables, failed to properly select test animals, and failed to establish accurate methods of testing for [canine hip dysplasia]." Walsh, *supra* note 16, at 427. *See also* Pfizer, Inc. v. Miles, Inc., 868 F. Supp. 437 (D. Conn. 1994). The *Pfizer* court found a study used as the basis for an establishment claim unreliable "because of the absence of a written protocol and scientific controls, including blinding, to ensure objectivity and accuracy of the data." *Id.* at 457. The same court also found a literal falsity where Pfizer used an article comparing its drug to a drug made by the competitor to establish that Pfizer's drug was superior to a *different* drug made by the competitor. *Id.* at 454-55.

evidence” that a defendant’s claim to the contrary is false. In *Zeneca Inc. v. Eli Lilly and Co.*,⁷³ Zeneca, maker of the breast cancer drug tamoxifen, sued Eli Lilly for making false claims pertaining to breast cancer prevention about its osteoporosis drug Evista. Evista had FDA approval for osteoporosis claims but not for breast cancer prevention claims. The court considered this relevant to its analysis:

The fact that the FDA has not approved [Evista] for breast cancer risk reduction does not conclusively demonstrate that the defendant’s claim that [Evista reduces] the risk of breast cancer is literally false under the Lanham Act because a... plaintiff must prove that the defendant’s efficacy claims are literally false, not simply that they fail to meet current federal licensing standards. However,... FDA’s conclusion [in FDA documents] that “[t]he effectiveness of [Evista] in reducing the risk of breast cancer has not yet been established” is *persuasive evidence* that Eli Lilly’s claims to the contrary are untrue.⁷⁴

Conversely, courts have held that FDA approval of a claim can be a defense to a section 43(a) suit. In *Cytoc Corp. v. Neuromedical Systems, Inc.*,⁷⁵ for example, rival manufacturers of cervical cancer detection devices disputed several product claims. Although the challenged product claims did “not correspond precisely to statements that the FDA has approved, [they were] similar enough to the approved statements for the [c]ourt to conclude, as a matter of law, that they are neither false nor misleading.”⁷⁶ And in another case, *American Home Products Corp. v. Johnson & Johnson*,⁷⁷ the court stated that: “If FDA approval of the precise label used by a drug manufacturer is a defense to a consumer’s product liability action, it should be, *a fortiori*, a defense to a competitor’s action under the Lanham Act.”⁷⁸ Therefore if an incredulous competitor sued

⁷³1999 WL 509471 at *1 (S.D.N.Y. July 19, 1999).

⁷⁵12 F. Supp.2d 296 (S.D.N.Y. 1998).

⁷⁶*Id.* at 301.

⁷⁷672 F. Supp. 135 (S.D.N.Y. 1987).

⁷⁸*Id.* at 144. In a somewhat disturbing case, Pfizer representatives told pharmacists that a competitor’s hypertension

Newco under section 43(a) for claiming that Taferomon stabilizes body fat levels, Newco would have a strong defense.⁷⁹

C. Deceptive or Misleading Product Claims

Imagine, however, that Newco advertises Taferomon as the “strongest” weight control drug available, and that a competitor cannot prove this statement literally false because Taferomon indeed has a higher laboratory “fat stabilization” rating than the competitor’s product. The competitor nevertheless may attempt to show that Newco’s statement is deceptive or misleading because it implies that Taferomon is the *most effective* weight control drug, whereas the fat stabilization rating does not correspond to effectiveness. Johnson & Johnson tried that approach when it disputed Rorer’s claim that Extra Strength Maalox Plus is the “strongest antacid there is.”⁸⁰ Because the statement was literally true based on laboratory tests for acid neutralization capacity, Johnson & Johnson offered consumer surveys to show that the product claim was misleading.⁸¹ Based on findings that only 7.5% of responses linked strength to superior relief, the court held that there was insufficient evidence of deception.⁸²

However, “[t]he probative value of a consumer survey is a highly fact-specific determination and a court may

medication can cause patients to die or become ill, despite the fact that the FDA had approved the drug as safe and effective. *See* Pfizer, Inc. v. Miles, Inc., 868 F. Supp. 437, 460 (D. Conn. 1994). Not surprisingly, the court found those statements by Pfizer representatives to be literally false and hence actionable under section 43(a). *See id.*

⁷⁹*Cf.* Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson-Merck Consumer Pharm. Co., 935 F. Supp. 327 (S.D.N.Y. 1996). In *Glaxo Warner-Lambert*, the plaintiff’s heartburn medicine had FDA approval for statements regarding relief, while the defendant’s heartburn medicine had FDA approval for statements regarding both relief and prevention. The court held that the defendant did not violate section 43(a) by instructing consumers through advertisements to read the labels to learn that the plaintiff’s medicine does not prevent heartburn. To hold otherwise would “eliminate the need for plaintiff to obtain FDA approval for labeling regarding heartburn prevention.” *Id.* at 331.

⁸⁰*See* Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc., 19 F.3d 125, 132-36 (3d Cir. 1994).

⁸¹*See id.*

⁸²*See id.* at 133-134 (noting that a Lanham Act plaintiff must show that the advertising “tends to deceive or mislead a *substantial* portion of the intended audience”) (emphasis added).

place such weight on survey evidence as it deems appropriate.”⁸³ Accordingly, one court recently stated that “[i]t is well established... that 25% is a sufficient level of confusion,”⁸⁴ while other courts have found that 23% confusion,⁸⁵ or even 15.5% confusion,⁸⁶ can support a section 43(a) claim.

IV. Remedies Awarded In Lanham Act Cases Against Food And Drug Companies

Lanham Act plaintiffs typically seek injunctions to stop their competitors from making offending false or misleading statements. Courts also have authority under the Lanham Act to award damages, although that power is rarely invoked in these cases.⁸⁷ Using their equitable discretion, however, courts have fashioned various other forms of relief.

One such remedy is corrective advertising, which is frequently awarded where the defendant targets its advertising toward doctors and other medical professionals.⁸⁸ In *Energy Four, Inc. v. Dornier Medical Systems, Inc.*,⁸⁹ for example, the manufacturer of refurbished electrodes for lithotripsy machines sued a leading supplier of such machines after the latter company distributed a brochure claiming that the refurbished electrodes had caused an “implosion and serious equipment damage.” After finding this statement false under section 43(a), the court ordered that a court-prepared notice be sent to all users of lithotripsy machines that

⁸³American Home Prods. Corp. v. Procter & Gamble Co., 871 F. Supp. 739, 760 (D.N.J. 1994). Moreover, the court stated, “[s]urveys must have certain hallmarks of reliability,” such as a representative sample and properly trained surveyors, and they must meet objective surveying and statistical standards. *Id.* at 760-61 (internal citation omitted).

⁸⁴Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 2000 WL 1946673 at *14 (D.N.J. Dec. 22, 2000).

⁸⁵McNeilab v. American Home Prods. Corp., 501 F. Supp. 517, 525, 527 (S.D.N.Y. 1980).

⁸⁶Coca-Cola Co. v. Tropicana Prods., Inc., 690 F.2d 312, 317 (2d Cir. 1982).

⁸⁷See 15 U.S.C. § 1117(a) (2000). See also *Alpo Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958 (D.C. Cir. 1990).

⁸⁸See generally Thomas C. Morrison, *Corrective Advertising As a Remedy for the False Advertising of Prescription Drugs and Other Professionally-Promoted Medical Products*, 49 FOOD & DRUG L.J. 385 (1994).

⁸⁹765 F. Supp. 724 (N.D. Ga. 1991).

could use the refurbished electrodes. Among other statements, the notice included a notice that there was “absolutely no evidence” regarding the claimed implosion. The court also included a disclaimer, noting that, “[t]he court expresses no opinion on the relative merits of new and refurbished electrodes or on whether or not it is within the standard of care prevailing in your communities to use refurbished electrodes.”⁹⁰ Similarly, in the *Alpo Petfoods* case regarding Ralston’s claims relating to canine hip dysplasia, the court ordered Ralston “to prepare and disseminate to those who received information concerning its [canine hip dysplasia] claims [*i.e.*, veterinarians] a corrective release in terms and in form to be approved by this court.”⁹¹

Courts have also required training sessions with employees of companies making false or misleading product claims as a remedy for those Lanham Act violations. The court in *Zeneca, Inc. v. Eli Lilly and Company*,⁹² for example, ordered the defendant to design and implement a training program for its sales representatives “to ensure that [they] are made aware of and adhere to [the court’s] decision and order and do not make claims in the field that [Evista] has been proven to reduce the risk of breast cancer or that it is comparable or superior to tamoxifen.”⁹³ The court in *Pfizer, Inc. v. Miles, Inc.*,⁹⁴ likewise ordered Pfizer to hold training sessions with its sales representatives so that they were “made fully of aware of the findings” of the court that Pfizer had violated section 43(a).⁹⁵

Courts have also exercised their discretion to order product recalls and to order the cancellation of outstanding orders. In *Upjohn Co. v. Riahom Corp.*,⁹⁶ the court ordered the defendant to recall its product and offending promotional materials that were in the possession of its packagers and sales representatives.

⁹⁰*Id.* at 733-735. *See also* Morrison, *supra* note 88, at 392-394.

⁹¹*Alpo Petfoods, Inc. v. Ralston Purina Co.*, 720 F. Supp. 194, 215 (D.D.C. 1989).

⁹²1999 WL 509471 at *42 (S.D.N.Y. July 19, 1999).

⁹³*Id.*

⁹⁴868 F. Supp. 437 (D. Conn. 1994).

⁹⁵*Id.* at 461.

⁹⁶641 F. Supp. 1209, 1226-27 (D. Del. 1986).

The court further required the defendant to cancel outstanding orders, to send a letter to customers who had outstanding orders, and to stop soliciting new orders until the company prepared new packaging and promotional materials.⁹⁷ Another court stopped short of a recall but ordered a defendant to send a letter “to all to whom [its mascara which claimed to be waterproof but was found not to be] has been distributed directing them to withhold further sales of [the mascara].”⁹⁸

V. Conclusion

The Lanham Act provides a flexible self-help remedy to food and drug companies that are harmed by unfair competition in the marketplace. But is it desirable for private litigation to become the *de facto* regulation of the industry? In an FDA regulation concerning a warning on OTC drug labels, the agency asserted that “it is in the best interest of the consumer, industry, and the marketplace to have uniformity in presentation and clarity of message.”⁹⁹ However, increased regulation through private litigation can send a muddled and inconsistent message to food and drug companies. Moreover, as one commentator wrote:

Lanham Act litigation is no panacea. Although the goal is to obtain quick relief, that outcome is not always achieved. A court may not grant a broad enough injunction to truly benefit the plaintiffs. Cases can become bogged down in discovery, which can quickly escalate litigation costs. Counterclaims are a common tactic. The plaintiff may not only lose its case, but it risks a counterattack against its own advertising. Legal fees can be quite high.¹⁰⁰

One party in the *American Home Products Corp. v. Johnson & Johnson*¹⁰¹ case suggested to the court

⁹⁷*See id.*

⁹⁸*Maybelline Co. v. Noxell Corp.*, 643 F. Supp. 294 (E.D. Ark. 1986), *rev'd*, 813 F.2d 901 (8th Cir. 1987) (reversing because venue was improper).

⁹⁹50 Fed. Reg. 51,400, 51,402 (1985).

¹⁰¹672 F. Supp. 135 (S.D.N.Y. 1987).

that a Lanham Act plaintiff acts as a “vicarious avenger of the public’s right to be protected from false advertising.”¹⁰² But as the court recognized, that party was not “suing... merely to vindicate the public interest in drug labeling.”¹⁰³ The company had its business interests in mind, and in that case was even asking for damages. This is why the role of the FDA enforcement cannot be pushed aside, or replaced by private litigation. “An action under the Lanham Act... is not the proper legal vehicle in which to vindicate the public’s interest in health and safety.”¹⁰⁴ Although many of the cases discussed herein involved disputes over product claims that did not place public health at risk, ensuring truthful labeling and advertising for food and drugs nevertheless plays a vital role in protecting public health and safety.

Surveys have repeatedly shown that Americans have great faith in the FDA.¹⁰⁵ While recognizing that budgetary limitations will always preclude the FDA from pursuing every violation, the agency, and not the courts, should be the foremost avenger of the public’s right to healthy and safe food and drugs. Lanham Act litigation, on the other hand, should remain a powerful tool for redressing economic harms.

¹⁰²*Id.* at 145 (internal quotation marks omitted).

¹⁰³*Id.*

¹⁰⁴*Id.* (citation omitted).

¹⁰⁵PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS – SECOND EDITION, 18-19 (1991) (stating that the public, “according to repeated... surveys, rates FDA among the federal agencies in which they have the greatest confidence”).